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**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellants	:	Dally, et al.,	)	Group Art Unit:
			)	1624
Serial No.	:	10/597,241	)	
International	:	January 18, 2005	)	Examiner:
Filing Date			)	Coleman, B.L.
			)	
US National Entry:		July 18, 2006	)	
			)	
Docket No.	:	X-16604M	)	
For	:	SELECTIVE ESTROGEN RECEPTOR MODULATORS FOR THE		
		TREATMENT OF VASOMOTOR SYMPTOMS		

**REPLY BRIEF (37 C.F.R. § 41.41) FOR DALLY, et al.**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA, 22313-1450

Sir:

This brief is submitted in reply to the Examiner's Answer filed in this case on  
March 2, 2011.

**REPLY REGARDING OBVIOUSNESS UNDER §103**

Appellants respectfully assert that the Examiner's theory for obviousness rests on a single prong: there is generic overlap in scope between the presently claimed compounds and that disclosed in the prior art (Grese I, II and/or III<sup>1</sup>).

The compounds of the instant invention are generically embraced by [Grese] in view of the interchangeability of the substitutions of the tetracyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example fluoro for the variable R1 as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Examiner's Answer at page 4, bridging to page 5. Appellants have asserted that in the context of the present invention (pharmaceutical compounds) generic overlap in scope with the prior art by itself is not legally sufficient to render Appellant's claims obvious and even if it were, further facts gleaned from Grese lead to a different conclusion.

For example, Appellants have asserted that Grese's teachings as a whole do not direct the skilled artisan to the presently claimed (for brevity) fluoro-substituted compounds but instead direct attention towards hydroxy- or hydroxy-substituted compounds. Appellants have cited to more than ten passages in Grese where statements of preference direct the artisan to hydroxy- and hydroxy-substituted compounds. In the Answer, the Examiner has either disregarded or ignored what Appellant has stated or continues to mischaracterize Grese.

With respect to disregarded arguments, the Examiner asserts that statements of preference with respect to chemical intermediates within Grese do not provide a teaching relevant to preferred final products. Appellants respectfully assert that this is not a logical or fair way to interpret Grese. Those preferred intermediates that Appellant has cited to in Grese are used to prepare preferred final products all of which are hydroxy- or hydroxy-substituted compounds. Grese does not contain any statements of preference for intermediates used to prepare fluoro-substituted compounds and does not contain any statements of preference for fluoro-substituted final products (more on these last two points

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<sup>1</sup> Grese I is a continuation of Grese II and Grese II is a division of Grese III. As such, all three patent disclosures, save the claims, are identical and will be referred to collectively herein as "Grese".

in paragraph immediately below). As such, Grese's teaching, when taken as a whole, do not lead the skilled artisan to the claimed subject matter.

With respect to the Examiner's mischaracterization of Grese, the Answer continues to insist that a sub-genus disclosed in Grese that includes fluoro-substituted compounds is a statement of preference for fluoro. Appellants assert that in the abstract an assertion that sub-genus = preferred without further analysis is flawed. In this particular case, that assertion is demonstrably false. Appellants have explained in their Brief that the sub-genus disclosure at dispute is not a statement of preference but instead a reflection of how Grese explains the synthesis of the compounds disclosed therein. Grese's explicit teaching on synthetic methodology can be summarized as follows:

- a) Grese's claimed derivatized hydroxy-substituted compounds are made from Grese's claimed hydroxy-substituted compounds;
- b) Grese's claimed hydroxy-substituted compounds are not prepared directly but are made from protected hydroxy-compounds;
- c) protected hydroxy-compounds, and the remainder of Grese's claimed compounds (which necessarily includes fluoro-substituted compounds but also necessarily excludes hydroxy- and derivatized hydroxy-compounds), can be prepared directly.

Appellants respectfully assert the Examiner has misinterpreted c) above for a statement of preference within Grese for fluoro-substituted compounds. When the facts are accurately distilled, Appellants respectfully assert that all that is left of the Examiner's obviousness rejection is generic overlap in scope with Grese where Grese strongly directs attention toward subject matter not presently claimed. Appellants respectfully assert that these facts are not sufficient to support a rejection under §103.

#### **ARGUMENT REGARDING OTDP**

Appellants respectfully assert that if the present claims are not obvious in view of Grese's entire disclosure, then they can't be obvious in view Grese's claims.

**SUMMARY**

Appellants respectfully request reversal of the present rejections and passage of the present case to issuance.

Respectfully submitted,

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